IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

COSMO TECHNOLOGIES LIMITED, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS LUXEMBOURG S.À R.L., Plaintiffs, v. MYLAN PHARMACEUTICALS INC., Defendant.	Civil Action No. 1:16-CV-40 (Keeley) Electronically filed: 03/14/2016

COMPLAINT

Plaintiffs Cosmo Technologies Limited ("Cosmo"), Valeant Pharmaceuticals International ("VPI"), and Valeant Pharmaceuticals Luxembourg S.à r.l. ("Valeant S.à r.l.") (collectively, "Plaintiffs"), for their Complaint against Defendant Mylan Pharmaceuticals Inc. ("Mylan Pharma"), hereby allege as follows:

PARTIES

1. Plaintiff Cosmo is an Irish corporation, having its principal place of business at Riverside II, Sir John Rogerson's Quay, Dublin 2, Ireland.

2. Plaintiff VPI is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

3. Plaintiff Valeant S.à r.l. is a Luxembourg corporation, having its principal place of business at 13-15 Avenue de la Liberté, L-1931 Luxembourg, Grand Duchy of Luxembourg.

4. Upon information and belief, Mylan Pharma is a corporation organized and existing under the laws of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. On information and belief, Defendant Mylan Pharma develops, manufactures, and packages numerous generic versions of branded pharmaceutical products for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

5. This is a civil action for infringement of U.S. Patent No. 7,410,651 ("the '651 patent"); U.S. Patent No. 8,293,273 ("the '273 patent"); U.S. Patent No. 8,784,888 ("the '888 patent"); and U.S. Patent RE 43,799 ("the '799 patent") (collectively, "patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Defendant Mylan Pharma by virtue of, *inter alia*, its incorporation under the laws of the State of West Virginia, and because it maintains a principal place of business in the State of West Virginia at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

8. This Court also has personal jurisdiction over Defendant Mylan Pharma by virtue of, *inter alia*, the fact that Mylan Pharma has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs.

9. Upon information and belief, Mylan Pharma has received more than 200 approvals for generic drug products and sells drug products throughout the United States, including in this District.

10. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

11. On August 12, 2008, the '651 patent, titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," was duly and legally issued. A copy of the '651 patent is attached hereto as Exhibit A.

12. Cosmo is the present owner of the '651 patent. Valeant S.à r.l. holds an exclusive license to the '651 patent.

13. On October 23, 2012, the '273 patent, titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," was duly and legally issued. A copy of the '273 patent is attached hereto as Exhibit B.

14. Cosmo is the present owner of the '273 patent. Valeant S.à r.l. holds an exclusive license to the '273 patent.

15. On July 22, 2014, the '888 patent, titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," was duly and legally issued. A copy of the '888 patent is attached hereto as Exhibit C.

16. Cosmo is the present owner of the '888 patent. Valeant S.à r.l. holds an exclusive license to the '888 patent.

17. On November 13, 2012, the '799 patent, titled "Controlled Release and Taste Masking Oral Pharmaceutical Composition," was duly and legally reissued. A copy of the '799 patent is attached hereto as Exhibit D.

18. Cosmo is the present owner of the '799 patent. Valeant S.à r.l. holds an exclusive license to the '799 patent.

ACTS GIVING RISE TO THIS ACTION

19. VPI holds New Drug Application ("NDA") No. 203634 for oral tablets containing 9 mg of the active ingredient budesonide, which are sold in the United States under the brand name "Uceris®." Uceris® is indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis.

20. Pursuant to 21 U.S.C. § 355(b)(1), the '651 patent, the '273 patent, the '888 patent, and the '799 patent are listed in the U.S. Food and Drug Administration's ("FDA") publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as covering Uceris® and its method of use.

21. Upon information and belief, Mylan Pharma submitted Abbreviated New Drug Application ("ANDA") No. 208851 ("Mylan Pharma's ANDA") to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, Mylan Pharma's ANDA seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of tablets containing 9 mg of budesonide ("Mylan Pharma Generic Product") prior to the expiration of the '651 patent, the '273 patent, the '888 patent, and the '799 patent.

22. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Mylan Pharma certified in ANDA No. 208851, *inter alia*, that the claims of the '651 patent, the '273 patent, the '888 patent, and the '799 patent are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale, and/or sale of the Mylan Pharma Generic Product.

23. Plaintiffs received written notification of Mylan Pharma's filing of its ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certifications directed to, *inter alia,* the '651 patent, the '273 patent, the '888 patent, and the '799 patent, in a letter dated January 29, 2016 and sent via Federal Express ("Mylan Pharma's Notice Letter").

24. Mylan Pharma's Notice Letter does not deny the validity of the '651 patent, the '273 patent, the '888 patent, or the '799 patent separate and apart from asserting noninfringement.

25. This action was commenced by Plaintiffs within 45 days of the date of receipt of Mylan Pharma's Notice Letter.

26. Mylan Pharma's Notice Letter included an accompanying Offer of Confidential Access ("OCA") to certain Mylan Pharma confidential information regarding the Mylan Pharma Generic Product. Plaintiffs subsequently, over the course of several weeks, negotiated with Mylan Pharma in an effort to agree on reasonable terms for Mylan Pharma's OCA. The parties were not able to reach agreement with respect to the revisions of the terms of Mylan Pharma's OCA that Plaintiffs' proposed.

27. To date, Mylan Pharma has not provided Plaintiffs with a copy of any portions of its ANDA or any information regarding the Mylan Pharma Generic Product beyond the information that was set forth in Mylan Pharma's Notice Letter.

28. This limited information relating to the Mylan Pharma Generic Product that was provided in Mylan Pharma's Notice Letter does not demonstrate that the Mylan Pharma Generic Product that Mylan Pharma is asking the FDA to approve for the sale in the U.S. will not fall within the scope of any issued claim of the '651 patent, the '273 patent, the '888 patent, and the '799 patent.

FIRST COUNT
(Infringement by Mylan Pharma of U.S. Patent No. 7,410,651)

29. Plaintiffs re-allege paragraphs 1-28 as if fully set forth herein.

30. Mylan Pharma's submission of ANDA No. 208851 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '651 patent under 35 U.S.C. § 271(e)(2)(A).

31. Moreover, if Mylan Pharma manufactures, uses, sells, offers for sale, or imports into the United States the Mylan Pharma Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '651 patent, including any applicable exclusivities or extensions, Mylan Pharma would further infringe the '651 patent under 35 U.S.C. § 271(a), (b), and/or (c).

32. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Mylan Pharma's ANDA No. 208851 be a date that is not earlier than the expiration of the term of the '651 patent, including any extension(s) granted by the U.S. Patent and Trademark Office ("PTO") pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '651 patent to which Plaintiffs are or become entitled.

33. Plaintiffs will be irreparably harmed by Mylan Pharma's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

34. Upon information and belief, Mylan Pharma was aware of the existence of the '651 patent and was aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '651 patent constituted an act of infringement of the '651 patent.

SECOND COUNT
(Infringement by Mylan Pharma of U.S. Patent No. 8,293,273)

35. Plaintiffs re-allege paragraphs 1-34 as if fully set forth herein.

36. Mylan Pharma's submission of ANDA No. 208851 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '273 patent under 35 U.S.C. § 271(e)(2)(A).

37. Moreover, if Mylan Pharma manufactures, uses, sells, offers for sale, or imports into the United States the Mylan Pharma Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '273 patent, including any applicable exclusivities or extensions, Mylan Pharma would further infringe the '273 patent under 35 U.S.C. § 271(a), (b), and/or (c).

38. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Mylan Pharma's ANDA No. 208851 be a date that is not earlier than the expiration of the term of the '273 patent, including any extension(s) granted by the PTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '273 patent to which Plaintiffs are or become entitled.

39. Plaintiffs will be irreparably harmed by Mylan Pharma's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

40. Upon information and belief, Mylan Pharma was aware of the existence of the '273 patent and was aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '273 patent constituted an act of infringement of the '273 patent.

THIRD COUNT
(Infringement by Mylan Pharma of U.S. Patent No. 8,784,888)

41. Plaintiffs re-allege paragraphs 1-40 as if fully set forth herein.

42. Mylan Pharma's submission of ANDA No. 208851 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '888 patent under 35 U.S.C. § 271(e)(2)(A).

43. Moreover, if Mylan Pharma manufactures, uses, sells, offers for sale, or imports into the United States the Mylan Pharma Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '888 patent, including any applicable exclusivities or extensions, Mylan Pharma would further infringe the '888 patent under 35 U.S.C. § 271(a), (b), and/or (c).

44. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Mylan Pharma's ANDA No. 208851 be a date that is not earlier than the expiration of the term of the '888 patent, including any extension(s) granted by the PTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '888 patent to which Plaintiffs are or become entitled.

45. Plaintiffs will be irreparably harmed by Mylan Pharma's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

46. Upon information and belief, Mylan Pharma was aware of the existence of the '888 patent and was aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '888 patent constituted an act of infringement of the '888 patent.

FOURTH COUNT
(Infringement by Mylan Pharma of U.S. Patent RE 43,799)

47. Plaintiffs re-allege paragraphs 1-46 as if fully set forth herein.

48. Mylan Pharma's submission of ANDA No. 208851 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '799 patent under 35 U.S.C. § 271(e)(2)(A).

49. Moreover, if Mylan Pharma manufactures, uses, sells, offers for sale, or imports into the United States the Mylan Pharma Generic Product, or induces or contributes to any such conduct, prior to the expiration of the '799 patent, including any applicable exclusivities or extensions, Mylan Pharma would further infringe the '799 patent under 35 U.S.C. § 271(a), (b), and/or (c).

50. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Mylan Pharma's ANDA No. 208851 be a date that is not earlier than the expiration of the term of the '799 patent, including any extension(s) granted by the PTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '799 patent to which Plaintiffs are or become entitled.

51. Plaintiffs will be irreparably harmed by Mylan Pharma's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

52. Upon information and belief, Mylan Pharma was aware of the existence of the '799 patent and was aware that the filing of its ANDA and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the '799 patent constituted an act of infringement of the '799 patent.

STATEMENT REGARDING PRIOR-FILED SUIT IN DELAWARE

53. Plaintiffs previously filed and served, on March 10, 2016, an action seeking to enjoin Mylan Pharma from infringing the '651 patent, the '273 patent, the '888 patent, and the '799 patent in the District of Delaware, and that action has been captioned C.A. No. 16-152 ("Mylan Pharma D. Del. Action"). There are four other patent infringement actions brought by

Cosmo, VPI, and Valeant S.à r.l that are presently pending in the District of Delaware and involve the patents-in-suit. These actions were filed against Par Pharmaceutical, Inc., Actavis Laboratories FL, Inc., Alvogen Pine Brook, LLC, and Lupin Limited and Lupin Pharmaceuticals, Inc., and have been captioned, respectively, C.A. No. 15-116-LPS, C.A. No. 15-164-LPS, C.A. No. 15-193-LPS, and C.A. No. 15-669-LPS (collectively, "Uceris D. Del. Actions"). The Mylan Pharma D. Del. Action has been designated a related case to the Uceris D. Del. Actions.

54. In the Mylan Pharma D. Del. Action, Plaintiffs alleged that the District of Delaware has personal jurisdiction over Mylan Pharma with regard to Plaintiffs' claims of patent infringement. On March 4, 2016, during the parties' negotiations related to Mylan Pharma's OCA, Mylan Pharma's outside counsel informed Plaintiffs that Mylan Pharma planned to contest personal jurisdiction over Mylan Pharma by the District of Delaware.

55. As stated above, Plaintiffs received written notification of Mylan Pharma's ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter dated January 29, 2016. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), a patent owner has 45 days from receipt of a written notification and accompanying § 505(j)(2)(A)(vii)(IV) certification ("ANDA Notice Letter") to file a suit in order to perfect its statutory right to a stay of FDA approval of an ANDA. Plaintiffs filed this action as a further protective measure with regard to this statutory right, in light of Mylan Pharma's representation regarding its intent to file a motion to dismiss Plaintiffs' complaint for lack of personal jurisdiction over Mylan Pharma by the District of Delaware in the Mylan Pharma D. Del. Action.

56. Due to the fact that Chief Judge Stark is presiding over the Uceris D. Del. Actions involving the patents-in-suit, judicial economy would be promoted, and Plaintiffs' choice of forum respected, if the claims against Mylan Pharma related to Plaintiffs' action for infringement of the patents-in-suit are addressed by Chief Judge Stark in the District of Delaware

57. Plaintiffs expect that personal jurisdiction over Mylan Pharma will be maintained in the District of Delaware and that their action against Mylan Pharma will proceed in that forum. *See, e.g.*, *Acorda Therapeutics, Inc. v. Mylan Pharms. Inc.*, 78 F. Supp. 3d 572, 587 (D. Del. 2015) (Stark, J.) (finding personal jurisdiction over Mylan Pharma by the District of Delaware), *appeal pending*, No. 15-1456 (Fed. Cir.) (oral argument heard on January 4, 2016); *see also Forest Labs., Inc. v. Amneal Pharms. LLC*, Civ. No. 14-508-LPS, 2015 U.S. Dist. LEXIS 23215 (D. Del. Feb. 26, 2015), *report and recommendation adopted*, 2015 U.S. Dist. LEXIS 39846 (D. Del. Mar. 30, 2015) (same). In that circumstance, this action would be unnecessary and may be voluntarily dismissed without prejudice in favor of continued prosecution of the Mylan Pharma D. Del. Action, transferred to the District of Delaware for consolidation with the Mylan Pharma D. Del. Action, or be subject to such other non-substantive disposition that would ensure maintenance of Plaintiffs' rights pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Mylan Pharma has infringed one or more claims of the '651 patent;

B. That Mylan Pharma has infringed one or more claims of the '273 patent;

C. That Mylan Pharma has infringed one or more claims of the '888 patent;

D. That Mylan Pharma has infringed one or more claims of the '799 patent;

E. That pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 208851 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall not be a date that is earlier than the latest expiration date of the patents-in-suit, including any applicable exclusivities or extensions;

F. That Mylan Pharma, its officers, agents, servants and employees, and those

persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling, or importing into the United States the Mylan Pharma Generic Product and any other product that infringes or induces or contributes to the infringement of one or more claims of the '651 patent, the '273 patent, the '888 patent, and the '799 patent prior to their expiration, including any exclusivities or extensions to which Plaintiffs are or become entitled;

G. That Plaintiffs be awarded the attorney fees, costs, and expenses that they incur prosecuting this action; and

H. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

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/s/ William A. Kolibash

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March 14, 2016